Supreme Court, U.S.
FILED
MAR 31 1998
CLERK

No. 97-1292

In The

Supreme Court of the United States

October Term, 1997

CRITIKON, INC.,

Cross-Petitioner,

v.

BECTON DICKINSON VASCULAR ACCESS, INC.,

Cross-Respondent.

On Conditional Cross-Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY IN SUPPORT OF CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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March 31, 1998

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

REPLY TO OPPOSITION 1

A. Confusion Exists As To What Is Required To Support A Finding Of Inequitable Conduct 1

B. Becton Dickinson's Opposition Exemplifies The Confusion That Exists In The Law 3

C. This Petition Presents A Purely Legal Question 4

D. The Undisputed State Of Uncertainty In The Law Presents A Compelling Reason For Granting This Petition 4

CONCLUSION 5

TABLE OF AUTHORITIES

Page(s)

CASES

Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253 (Fed.Cir. 1997).....1, 2, 3, 4

Driscoll v. Cebalo, 731 F.2d 878 (Fed. Cir. 1984).....*passim*

FMC Corp. v. Manitowoc Co., 835 F.2d 1411 (Fed.Cir. 1987)..... 3

Kingsdown Medical Consultants v. Hollister Inc., 863 F.2d 867 (Fed.Cir. 1988).....1, 2, 3, 4

Warner-Jenkinson Co. v. Hilton Davis Chem. Co., ___ U.S. ___, 117 S.Ct. 1040 (1997) 4

REPLY TO OPPOSITION

The importance of the first question presented in Critikon's conditional cross-petition for a writ of certiorari, namely, the correct legal standard governing whether a patent applicant can be found guilty of inequitable conduct, *i.e.*, by committing fraud on the PTO, is not denied by Becton Dickinson. Nor does Becton Dickinson deny that this legal question is squarely presented by the facts of this case. And importantly, Becton Dickinson's opposition highlights the hopeless state of confusion created by the Federal Circuit's decision in *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed.Cir. 1997), on the issue of inequitable conduct. For all of these reasons, this Court should grant certiorari to address the proper legal standard governing the adjudication of a charge of inequitable conduct, a charge that occurs in nearly every patent infringement action.

A. Confusion Exists As To What Is Required To Support A Finding Of Inequitable Conduct

As Critikon established in its petition, old Federal Circuit cases, such as *Driscoll v. Cebalo*, 731 F.2d 878 (Fed.Cir. 1984), held that negligence on the part of a patent applicant was sufficient to support a finding of inequitable conduct. Under the rule of *Driscoll*, a patent applicant could be found guilty of inequitable conduct – fraud on the PTO – if he was merely negligent in his dealings with the PTO. 731 F.2d at 885.

Later, the Federal Circuit thoroughly revisited this issue in its *en banc* decision in *Kingsdown Medical Consultants v. Hollister Inc.*, 863 F.2d 867 (Fed.Cir. 1988). In

Kingsdown, as Becton Dickinson concedes, the Federal Circuit squarely rejected the negligence standard of *Driscoll*. 863 F.2d at 876. Specifically, the *Kingsdown* court held that the finding of even "gross" negligence is insufficient to support a finding of inequitable conduct. 863 F.2d at 876. Thus, the rule of *Driscoll* has long been thought to be thoroughly discredited.

The central problem here that calls for this Court's attention is the Federal Circuit's apparent revival of *Driscoll* as controlling law, throwing the rule of law governing the adjudication of a charge of inequitable conduct into a state of utter confusion. Thus, as matters now stand, no one knows what the controlling law is – the rule of *Driscoll*, long thought to be discredited but now apparently resurrected by the *Critikon* panel, or the rule of *Kingsdown* that has been in place for nearly a decade.

It is telling that Becton Dickinson essentially ignores the Federal Circuit's citation to *Driscoll v. Cebalo*, 731 F.2d 878 (Fed.Cir. 1984). Certainly, there can be no doubt that the *Critikon* panel, in citing *Driscoll*, appeared to revive the "negligence" standard for determining whether a patent applicant can be found guilty of inequitable conduct. 120 F.3d at 1256. Unquestionably, as the Federal Circuit stated in *Critikon*:

> For example, intent may be inferred where a patent applicant . . . *should have known* [ ] that withheld information would be material. . . . *Driscoll v. Cebalo*, 731 F.2d 878, 885, 221 USPQ 745, 751 (Fed.Cir. 1984).

Id. (emphasis added).

B. Becton Dickinson's Opposition Exemplifies The Confusion That Exists In The Law

In an attempt to prop up the *Critikon* decision, Becton Dickinson essentially argues that when the *Critikon* panel cited to *Driscoll* on the level of wrongful intent required for a finding of inequitable conduct, it really intended to cite *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411 (Fed.Cir. 1987). (Opposition at 11). This alleged misunderstanding over what authorities the Federal Circuit intended to rely on itself shows that the *Critikon* decision has generated hopeless uncertainty in the law. Moreover, even if the *Critikon* panel meant to apply the holding of *FMC*, rather than that of *Driscoll*, as it said it did, Becton Dickinson's argument fails because the Federal Circuit in *Kingsdown*, along with its rejection of *Driscoll*, thoroughly rejected the *FMC* legal standard for adjudicating the issue of inequitable conduct. 863 F.2d at 876.

In an attempt to support the revival of the negligence standard, Becton Dickinson creates even more confusion by pointing to the language in *Kingsdown* that "gross negligence alone *does not mandate* a finding of intent to deceive." *Kingsdown*, 865 F.2d at 876 (emphasis added). According to Becton Dickinson, this language left open the possibility that the necessary level of wrongful intent could be based on – but was not mandated by – a finding of negligence on the part of the patent applicant. (Opposition at 9-10). The *Kingsdown* court, however, put this possibility to rest in the very next paragraph of the opinion when it unequivocally held that "gross negligence *does not*" justify an inference of an intent to deceive. *Kingsdown*, 863 F.2d at 876 (emphasis added). Plainly, the

argument that *Critikon* overruled this long settled rule of *Kingsdown* is yet another ground for confusion.

C. This Petition Presents A Purely Legal Question

Becton Dickinson's long discussion of the facts of this case is makeweight. The central question presented by Critikon is purely a legal question, and it is one that Becton Dickinson does not deny is presented by the facts of this case. Thus, Becton Dickinson's discussion of the facts is irrelevant to the critical issue here, namely, whether the Federal Circuit's decision in *Critikon* adopted the proper legal standard to decide whether a patent applicant committed inequitable conduct in the PTO.

D. The Undisputed State Of Uncertainty In The Law Presents A Compelling Reason For Granting This Petition

In sum, the abrupt and unexplained change in direction of the *Critikon* panel has created a state of uncertainty in the law. This uncertainty affects inventors and investors, as well as the public that can attain significant benefits from costly and risky research and development that hinges on the ability to obtain sound, enforceable patent protection. *See, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, ___ U.S. ___, ___, 117 S.Ct. 1040, 1045 (1997). In the presence of the confusion created by the *Critikon* decision and in the absence of this Court's action, research and development that depends on sound patent protection will be shelved to the public's detriment.

CONCLUSION

For the foregoing reasons, Critikon's conditional cross-petition for a writ of certiorari should be granted.

Respectfully submitted,

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